

This Letter Contract is being issued by the DLA Troop Support, Construction & Equipment (C&E) Supply Chain, to Battelle Memorial Institute under Contract Number SPE8EJ-20-D-0501 in order to support the US Government response to the Coronavirus Pandemic termed “COVID-19”. The authority governing this Contract is 10 U.S.C. 2304(c)(2), FAR Part 6.302-2, Unusual and compelling urgency. As this Letter Contract also meets the definition of an Undefined Contract Action (UCA), DFARS 217.74 is applicable.

The Performance Work Statement (PWS), to be supported by Battelle Memorial Institute (“Battelle”), includes turn-key type Services for operations, maintenance, and repairs of the Critical Care Decontamination System (CCDS) developed by Battelle.

In performing this Letter Contract, the Contractor is not authorized to make expenditures or incur obligations exceeding \$400,000,000.00. The ceiling for this Letter Contract is \$400,000,000.00. Additional authorizations and funds may be required during performance of this Letter Contract, but the ceiling remains \$400,000,000.00 unless changed in writing by the Contracting Activity.

On March 29, 2020, the United State (US) Food and Drug Administration (FDA) issued an Emergency Usage Authorization (EUA) for the Battelle CCDS specifically for use in decontaminating compatible N95 or N95-equivalent¹ respirators (“compatible N95 respirators”) for reuse by healthcare personnel (HCP) to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of respirators during the COVID-19 virus.

The Federal Emergency Management Agency (FEMA) and the US Health & Human Services (HHS) have designated the Defense Logistics Agency (DLA) as its Contracting Activity to procure the Battelle CCDS along with the required Services to operate and maintain the units. FEMA will provide DLA a Mission Assignment (MA) or HHS will provide DLA an Inter-Agency Agreement (IAA) with an appropriate Line of Accounting (LOA) to fund all DLA procurement actions, which will be covered by the DLA Working Capital Fund (DWCF).

DLA will execute procurement of the CCDS equipment from Battelle using an existing Contract vehicle in the C&E Supply Chain. The DLA Tailored Logistics Support Program (TLSP) Contractor executing the purchase will provide transportation and logistical support for movement of the CCDS equipment to the desired destination specified by FEMA or HHS. Under this arrangement, Battelle will act as a subcontractor to the DLA prime contract holder; successful execution, given the breadth of this mission to provide support for the COVID-19 virus, will require regular/recurring communication between its prime contractor and Battelle. DLA also intends to process requirements for repair parts, spares, and accessories under its existing Contract vehicle, which will ultimately be sourced/supplied by Battelle as subcontractor to the DLA TLSP prime contractor. Although the equipment purchases are outside the scope of this letter contract, there is a close relationship between the equipment purchases and the requirements under this letter contract. Further, the Warranty for the equipment purchase will be covered under the Warranty Clauses incorporated in the Contract for the DLA TLSP prime contractor, which will flow-down to Battelle as the subcontractor. FEMA or HHS will take possession and

ownership of the CCDS once they Systems are transported to their first designated location of priority or required delivery point.

DLA Troop Support C&E intends to issue multiple Task Orders (TOs) to Battelle under this Letter Contract once FEMA or HHS determines the specific locations (i.e. City, State, and County) where the CCDS equipment will be deployed. Battelle may invoice against specific Task Orders in conjunction with a schedule provided by the Contracting Officer in the Task Orders. There is no Guaranteed Minimum dollar value or Task Orders established for this Contract, which will be a Requirements Contract.

The DLA Troop Support C&E Supply Chain is the Contracting Activity and will perform all Administrative Contracting functions unless assistance is needed from the Defense Contract Management Agency (DCMA). Specific documentation and evidentiary matter as required by the EUA issued by the FDA shall be provided to the Contracting Officer to ensure Battelle is operating in accordance with the EUA.

This Letter Contract and all Task Orders will be Rated in accordance with the Defense Priority and Allocation System (DPAS). The specific Rating assigned is DO-C9 unless another Rating is assigned during performance of this Contract.

The Representations and Certifications of Battelle Memorial Institute registered in the System for Award Management (SAM) under Cage Code: 79986 are applicable to this Contract.

The following FAR and DFARS Clauses apply and will be included in this Letter Contract.

FAR 52.203-13 - Contractor Code of Business Ethics and Conduct

FAR 52.204-7 -System for Award Management

FAR 52.204-14 – Service Contract Reporting Requirements

FAR 52.209-6 - Protecting the Government’s Interest When Subcontracting with Contractors Debarred Suspended, or Proposed for Debarment

FAR 52.214-15 – Service Contract Reporting Requirements for Indefinite Delivery Contracts

FAR 52.212-4 - Contract Terms And Conditions – Commercial Items

FAR 52.216-18 – Ordering

Ordering (Oct 1995)

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from *April 9, 2020* through *April 9, 2022*.

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) If mailed, a delivery order or task order is considered “issued” when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of clause)

52.216-22 – Indefinite Quantity

52.216-23 - Execution and Commencement of Work

52.216-24 - Limitation on Government Liability (Full Text)

Limitation of Government Liability (Apr 1984)

(a) In performing this contract, the Contractor is not authorized to make expenditures or incur obligations exceeding \$400,000,000.00 dollars.

(b) The maximum amount for which the Government shall be liable if this contract is terminated is \$500,000.00 dollars.

(End of clause)

FAR 52.216-26 – Payments of Allowable Costs Before Definitization

FAR 52.222-41 – Service Contract Labor Standards

FAR 52.222-42 – Service Contract Act

FAR 52.222-49 – Service Contract Labor Standards-Place of Performance Unknown

FAR 52.222-50 – Combating Trafficking In Persons

FAR 52.222-55 - Minimum Wages Under Executive Order 13658

FAR 52.232-17 – Interest

DFARS 252.232-7003 - Electronic Submission of Payment Requests and Receiving Reports

DFARS 252.232-7006 - Wide Area Workflow Payment Instructions

DFARS 252.232-7011 – Payments in Support of Emergencies and Contingency Operations

CONTRACT DEFINITIZATION (DEC 2012)

(a) A Cost Plus Fixed Fee Contract is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the undefinitized contract action, (2) all clauses required by law on the date of execution of the definitive contract action, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit a Cost and Fee and certified cost or pricing data supporting its proposal.

(b) The schedule for definitizing this contract action is as follows *180 days - beginning on the date on which the contractor submits a qualifying proposal and the Contracting Officer obtains approval from the Head of the Contracting Activity (HCA) to enter into an Undefinitized Contracting Action (UCA).*

(c) If agreement on a definitive contract action to supersede this undefinitized contract action is not reached by the target date in paragraph (b) of this clause, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with Subpart 15.4 and Part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any event, the Contractor shall proceed with completion of the contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, the contract shall be governed by ☐

(i) All clauses required by the FAR on the date of execution of this undefinitized contract action for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);

(ii) All clauses required by law as of the date of the Contracting Officer's determination; and

(iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (c)(1) of this clause, all clauses, terms, and conditions included in this undefinitized contract action shall continue in effect, except those that by their nature apply only to an undefinitized contract action.

(d) The definitive contract resulting from this undefinitized contract action will include a negotiated *Cost Plus Fixed Fee* pricing arrangement in no event to exceed *the Contract ceiling of \$400,000,000.00.*

(End of clause)

Additional FAR and DFARS clauses may be added during the course of performance under this letter contract; Battelle agrees that these may be added unilaterally by the Contracting Officer and agrees to sign any modification adding such clause(s).

The following is a detailed proposal provided by Battelle that is hereby incorporated into this Letter Contract:

Performance Work Statement (PWS) for Operations of N95 Respirator Decontamination systems

1.0 Objective

The primary purpose of this PWS is to execute a process to decontaminate N95 respirators using a verified decontamination process.

2.0 Decontamination Process

2.1 The Contractor shall perform decontamination of N95 respirators

2.2 The Contractor will perform decontamination process at site locations determined by the Government.

2.3 The Contractor shall perform work in accordance with the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for the emergency use of the Battelle ^{CCDSTM} Critical Care Decontamination SystemTM (hereafter “the Battelle Decontamination System”) for the use in decontaminating compatible N95 or N95-equivalent respirators for use by healthcare personnel (HCP) to prevent exposure to pathogenic airborne particulates. The Battelle CCDSTTM systems which includes custom designed decontamination shelters, each with a capacity to hold up to 10,000 FFRs per decontamination cycle.

2.3.1 The decontamination process shall use commercially available vapor generator with an Environmental Protection Agency (EPA) registered sterilant. The system includes individual decontamination shelters, housing the primary decontamination chamber and an anteroom for donning and doffing of PPE prior to entering the decontamination chamber.

2.3.2 The CCDSTTM is configured for regional deployment, capable of achieving a throughput of up to 80,000 PPE units/day, with a basic logistical load to sustain operations for two weeks and indefinitely with weekly resupply of consumable

stocks. Although the CCDS can achieve a throughput of 80,000 PPE units/day, the EUA from the Food & Drug Administration states Battelle is authorized to decontaminate up to 10,000 compatible N95 respirators per chamber load, consistent with the data provided to FDA. Battelle shall provide FDA weekly reports, including data according to a testing plan (including data from chemical indicators and biological indicators) for scale-up reviewed by FDA, regarding the decontamination of compatible N95 respirators, including any reductions in decontamination ability. Battelle shall provide FDA, in advance of establishing satellite facilities where Battelle will perform decontamination using the Battelle Decontamination System, confirmation that all chambers, critical parameters, logistics, processes, containment systems, and labeling are identical and in place at all satellite facilities. After implementation, at the current and all satellite facilities, if Battelle demonstrates any reduction in decontamination ability for a given site, Battelle shall immediately notify FDA.

2.4 Contractor shall provide a standardized process with documented procedures in accordance with FDA EUA issued March 29, 2020.

2.4.1.1 Contractor shall establish an operations center to manage all deployed CCDSTM systems to include Site coordination, Delivery schedule, Resources, Training, Supply chain management, and other Logistics.

2.4.2 Contractor shall define decontamination procedures to include PPE requirements for personnel performing decontamination services.

2.4.2.1 Receipt of contaminated PPE

2.4.2.1.1 Contractor shall provide process for receipt of contaminated PPE from a medical facility.

2.4.2.2 Dirty Chamber Entry

2.4.2.2.1 Contractor shall define process for dirty entry and unpackage of contaminated N95 PPE.

2.4.2.2.2 Contractor shall provide Conex chamber environment that maintains negative pressure when in use.

2.4.2.2.3 Contractor shall provide disposal procedures for biohazard bags in dirty chambers.

2.4.2.3 Dirty Chamber Exit

2.4.2.3.1 Contractor shall provide plan for team exiting dirty chamber.

2.4.2.3.2 Contractor shall provide process for decontamination of contractor PPE upon exit from dirty chamber.

2.4.2.3.3 Contractor shall provide disposal process for hazardous waste.

2.4.2.3.4 Contractor shall provide storage for PAPR equipment.

2.4.2.3.5 Contractor shall provide showers.

2.4.2.4 Clean Entry After Decontamination

2.4.2.4.1 Contractor shall define process for chamber re-entry following each decontamination cycle.

2.4.2.4.2 Contractor shall perform low level monitoring of H₂O₂ concentrations prior to chamber re-entry.

2.4.2.4.3 Contractor shall provide carrying system for clean PPE.

2.4.3 VPHP Decontamination Procedures

2.4.3.1 Contractor shall monitor VPHP generation to meet minimum cycle parameters for successful decontamination.

2.4.3.2 Contractor shall define process for chamber aeration.

2.4.3.3 Contractor shall define process for management of Battelle
Decontamination System exhaust system.

2.4.4 Packaging Clean PPE

2.4.4.1 Contractor shall provide a process for packing clean PPE.

2.4.4.2 Contractor shall measure VPHP concentrations prior to packaging clean
PPE.

2.4.5 Inventory Management and Chain of Custody

2.4.5.1 Contractor shall provide an inventory control system to log in / out all PPE
received at the site.

2.4.5.2 Contractor shall provide labeling system to control inventory in dirty
chambers.

2.4.5.3 Contractor shall use clean labeling and return to transport container for
return to medical facility.

2.4.5.4 Contractor shall maintain CoC documentation that includes results from
all operational cycles.

2.4.6 Contractor shall execute quality assurance to ensure PPE is decontaminated and
verified using prescribed processes.

3.0 Program Management

3.1 Contractor shall provide operations management plan.

3.2 Contractor shall collect and compile data for use in operational efficiency and expansion of
the system use.

3.3 Contractor must notify the Contracting Officer of all key personnel engaged with the
Contract inclusive of Task Orders. Notification must also be provided to the Contracting
Officer if/when key personnel are replaced.

3.4 Contractor shall provide Monthly Status Reports.

- 3.4.1 A monthly status report shall provide a detailed status the decontamination services executed (i.e. # of units per day) as well as capture an overall status of the Operation. A minimum decontamination of 10,000 units per day is required for each site specific Task Order.
- 3.4.2 The contractor shall deliver the report on a date mutually agreed upon by the contractor and the client. Specific format, and any additional content not specified in this section, shall be mutually agreed upon by the contractor and client; this format shall be established No Later Than (NLT) 5 days after award.

4.0 Staffing the Decontamination Process of Personal Protective Equipment (PPE)

- 4.1 The Contractor shall provide trained staff to operate the Battelle Decontamination System on a 24/7 schedule.
- 4.2 The Contractor shall provide a staffing plan.
- 4.3 The Contractor shall provide staff trained in a standardized process to include:
 - 4.3.1 System operation including the packing and unpacking of PPE to be processed and inventory tracking;
 - 4.3.2 Staff shall work in PPE;
 - 4.3.3 Staff must pass a Medical Clearance to perform work;
 - 4.3.4 Staff must have a PAPR Fit test;
 - 4.3.5 Staff shall be offered Hep-B vaccination; and
 - 4.3.6 Staff shall perform work extended shifts as required.

5.0 Training Plan

- 5.1 Contractor shall develop and maintain a training plan.
- 5.2 Contractor shall perform training for staff.
- 5.3 Required curriculum

- 5.3.1 Air Purifying Respirator (WBT ESHQ_HS-100S_WBT) (1 hr)
- 5.3.2 PAPR Video (WBT ESHQ_HS-338_WBT) (0.25 hr)
- 5.3.3 Bloodborne Pathogens (WBT ESHQ_EP-200) (1 hr)
- 5.3.4 Personal Protective Equipment (WBT ESHQ_BCO-0017) (0.25 hr)
- 5.3.5 Hazard Communication (WBT ESHQ_BCO-0014) (0.5 hr)
- 5.3.6 Fire Extinguisher Awareness (WBT ESHQ_HS-141) (0.75 hrs)
- 5.3.7 DOT Hazmat Shipping Training – Infectious Waste, Li-Ion Batteries (1.5 hrs)
- 5.3.8 Forklift Training (optional, based on site) (N/A for now)
- 5.3.9 Review of SARS-CoV-2 fact sheet (FACT-100 in Pilgrim) (Signature Only)

6.0 Government Property/Equipment

6.1 Government Furnished Property (GFP) or Government Furnished Equipment (GFE). There is currently no GFP or GFE anticipated under this Letter Contract. Any potential GFP/GFE shall be handled in accordance with Federal Acquisition Regulation (FAR) 52.245-1.

6.2 Contractor Acquired Property (CAP). Any potential CAP shall be handled IAW FAR 52.245-

1. Government acceptance of CAP shall be made by the ACOR. Copies of the approved forms shall be provided with the Status Reports.

7.0 Security Requirements

7.1 The Government anticipates that access to classified data and information up to and including SECRET level may be required in performance of this work. Contractor personnel requiring access to classified information will have appropriate security clearances.

7.2 Security specifications applicable to performance of the TO will be expressed in a DD Form 254.

8.0 Travel and Other Direct Costs

8.1 Travel

- 8.1.1 Travel is anticipated in support of PWS requirements following Joint Travel Regulations for lodging, meals and incidental expenses as the guidance for reimbursement to the contractor.
- 8.1.2 The Government may provide military or federal-assisted transport of contractor systems, materials, and personnel to and from designated locations on an as-needed basis, inclusive of items incidental to the place of performance.
- 8.1.3 The Government will arrange for the contractor to have access to all necessary locations and installations including hospitals and medical facilities necessary to complete all aspects of the tasks.

8.2 Other Direct Costs (ODC)

- 8.2.1 The contractor will be required to purchase ODCs in performance of this TO. Examples of ODCs anticipated include CCDSTM set up materials, components, consumables, and other supplies; software licenses; and computer equipment. Any items purchased under this TO will be CAP and subject to Section 6.2 of this PWS.

Please provide acceptance, I will acknowledge and then you can begin performance.